EXHIBIT B2-A

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF ALBANY

People of the State of New York

Plaintiffs

v.

Pharmacia Corporation

Defendant

Index No. 904-03
RJI 01-03-075848
Hon. Louis C. Benza

People of the State of New York

Plaintiffs

v.

GlaxoSmithKline, P.L.C., et al.

Defendants

Index No. 905-03

People of the State of New York

Plaintiffs

v.

Aventis Pharmaceuticals, Inc.

Defendant

Index No. 1150-03

CONSOLIDATED MEMORANDUM OF LAW IN SUPPORT OF STATE'S OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

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SUMMARY OF THE STATE'S OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

The State of New York commenced these actions alleging that three pharmaceutical manufacturers, Aventis Pharmaceuticals Inc. ("Aventis"), SmithKlineBeecham, Inc. d/b/a GSK ("GSK")[1] and Pharmacia Corp.("Pharmacia"), each engaged in (1) deceptive business practices in violation of General Business Law ("GBL") § 349; (2) repeated or persistent fraud contrary to Executive ("Exec.") Law § 63(12); (3) commercial bribery, prohibited by Penal Law § 180.00, and (4) unacceptable practices in violation of the Medicaid Anti-Kickback regulation, 18 N.Y.C.R.R. § 515.2(b)(5). The complaints also allege that each defendant obtained state funds for themselves or another through false statements contrary to Social Services ("Soc. Serv.") Law § 145-b. The cases were removed to federal court, they have been remanded to this Court, and they were consolidated for pre-trial purposes. Each defendant has moved to dismiss the State's complaints in their entirety.

The essential facts are undisputed. Each defendant knew when it reported pricing information to a commercially available price compendium, that the compendium would base its published "average wholesale prices" on the defendant's pricing information, and that federal and state government then would use the reported prices to calculate reimbursements to health care providers for dispensing and administering certain drugs under Medicare Part B, Medicaid and New York State's Elderly Pharmaceutical Insurance Coverage Program ("EPIC"). Each manufacturer consistently reported amounts which bore no relation to the price paid for their drugs by health care providers and middlemen. Rather, the amounts reported were grossly inflated by defendants to maximize the providers' profits, *i.e.*, the difference between the amount the provider pays for a drug and the reimbursement the government and beneficiaries pay the provider. The manufacturers use the existence of this guaranteed profit to market their drugs, a practice known as "marketing the spread."

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[1]Pursuant to an agreement of the parties, the State has moved to dismiss voluntarily Glaxo Wellcome, Inc. with prejudice and GlaxoSmithKline plc without prejudice.

Defendants' false statements concerning the amount health care providers and middlemen pay for defendants' drugs caused substantial economic injury to New York consumers and the State of New York. Because defendants reported inflated prices for Medicare covered drugs, Medicare Part B beneficiaries, who are elderly and infirm, pay inflated amounts as copayments for prescription drugs administered outside a hospital setting, including those administered by injection or infusion by physicians, such as anti-cancer chemotherapy drugs and anti-emetics, which control nausea and vomiting caused by the chemotherapy. Because defendants reported fictitious wholesale prices for Medicaid- and EPIC-covered drugs, the State of New York has made excessive reimbursements to pharmacists. In addition, EPIC beneficiaries pay inflated amounts as copayments for covered drugs.

Defendants brazenly do not deny that their reported prices were completely divorced from the ordinary meaning of the statutory phrase "average wholesale price." To the contrary, defendants argue that government knowledge that at least some drug manufacturers were reporting amounts greater than the prices paid by middlemen or health care providers meant that all drug manufacturers had unfettered discretion to report any amount they wished. Defendants conclude that, because the government intended drug manufacturers to report inflated and fictitious wholesale prices, the complaints should be dismissed "as a matter of law."

Defendants' argument is without merit and should be rejected. This argument contravenes the plain language of the statute. Nothing in the meager legislative history of the "average wholesale price" provision, enacted in 1997, authorizes unbridled reporting of false statements. Quite the contrary, the legislative history indicates Congress was aware that Medicare was overpaying for drugs and that it needed to rectify the problem in the future. Defendants cite various examples of Congressional action and inaction after the enactment of the "average wholesale price" provision to somehow excuse their false reporting. Defendants' post-enactment history has no power to counter the plain meaning of a statute. As one federal court stated in rejecting the same argument, "[t]he fact that Congress has failed to disturb the widespread practice on the part of pharmaceutical companies of grossly overstating their

average wholesale prices cannot be read as a clear and manifest intention to grant immunity from state regulation of such fraudulent practices." *In re Pharmaceutical Industry Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 187 (D. Ct. Mass. 2003) ("*Pharma. Indus.* MDL").

Bereft of support from traditional sources of statutory construction, defendants resort to policy arguments. They suggest that the government consented to the pharmaceutical companies' fictitious reporting to provide a (potentially unlimited) subsidy to providers above their fee for professional services. A policy argument cannot disturb the ordinary meaning of plain language, especially when such meaning is reasonable and consistent with the purpose of the statute, and defendants cannot offer any authority for their policy argument in statutory language or legislative history. Quite the contrary, their policy argument cannot coexist with the congressional mandates to the Health Care Financing Administration ("HCFA") which shaped its promulgation of the average wholesale price standard, later enacted by Congress. Defendants' policy argument is unsupported and unreasonable. As another federal court stated in rejecting this argument, "[t]he suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians, is to say the least, unusual." *In re Lupron Marketing and Sales Practices Litigation*, No. MDL.1430, 01-CV-10861-RGS, 2003 WL 22839966, *5 (D. Mass. Nov 25, 2003) ("*Lupron* MDL"). In sum, the defendants' motion to dismiss based on an unsupported policy argument must be rejected.

Defendants also argue that their scheme is not the type of conduct prohibited by the statutes on which the State relies. Their position is contrary to the language and broad remedial purpose of the statutes and to the case law. Defendants baldly misstate the elements of the State's claims. For example, the claims under GBL § 349 and Exec. Law § 63(12) do not require a showing of intent to defraud, bad faith, detrimental reliance or injury. Nor do the State's claims for commercial bribery, Medicaid kickback or violations of the Social Service Law partake of any of these elements of common law fraud. Defendants' restrictive interpretation of these statutes, moreover, is contrary to the Legislature's intent

that they be liberally construed to achieve the protections against deceptive practices that the Legislature intended.

Finally, defendants suggest that the State's claims should be dismissed because they are not pleaded with sufficient detail. Defendants' scheme itself is fully described in the complaints, giving defendants more than adequate notice of their actions that lie at the heart of the State's claims. The claims asserted by the State do not require more detailed pleading under CPLR 3016(b). And even if a claim does fall within this section, the State's complaint is pleaded with sufficient detail, especially because defendants concealed the real prices they charged providers and middlemen, and defendants do not deny providers paid substantially less than the "average wholesale price." Defendants – and only they – know precisely the amount providers paid for their (and competitors') products. In the event the Court believes a more detailed pleading is warranted, however, it should allow the State discovery to ascertain the facts needed to plead the details of the defendants' admitted scheme, rather than dismiss the complaints outright.

STATEMENT OF THE FACTS

In deciding defendants' CPLR 3211 motion to dismiss, the Court must afford the State's complaints a liberal construction. CPLR § 3026 ("[p]leadings shall be liberally construed"); *Goshen v. Mutual Life Insurance Company of New York*, 98 N.Y.2d 314, 326 (2002); *Leon v. Martinez*, 84 N.Y.2d 83, 87 (1994). Accordingly, a court is required to "accept the facts as alleged in the complaint as true, accord plaintiffs the benefit of every possible favorable inference, and determine only whether the facts as alleged fit within any cognizable legal theory." *Leon v. Martinez*, 84 N.Y.2d at 87-88; *See also Sokoloff v. Harriman Estates Development Corp.*, 96 N.Y.2d 409, 414 (2001); *Hopkinson v. Redwing Construction Co.*, 301 A.D.2d 837 (3d Dept. 2003). Furthermore, Rule 3211(a)(1) motion to dismiss on the ground that the action is barred by documentary evidence "may be appropriately granted only where the documentary evidence utterly refutes plaintiff's allegations, conclusively establishing a defense as a

matter of law." *Goshen v. Mutual Life Insurance*, 98 N.Y.2d at 326; *Leon v. Martinez*, 84 N.Y.2d at 88; *Hopkinson v. Redwing Construction Co.*, 301 A.D.2d at 837-38. Defendants' collection of press clippings, proposed and promulgated federal regulations and comments, a few governmental studies, one sentence from a footnote in a more than decade-old brief, a radio address by former President Clinton and fragmentary remarks extracted from Medicare's complex legislative and administrative history, do not meet this standard.

The complaints set forth the following factual allegations which must be taken as true for the purpose of deciding defendants' motions. (When individual complaints are cited, the abbreviation "Compl." will be preceded by "Av." for Aventis, "GSK" for SmithKline Beecham and "Pharm." for Pharmacia.)

A. The Health Care Plans

Medicare is a health insurance program created by the federal government for the elderly and disabled. 42 U.S.C. §§ 1395, *et seq*. The vast majority of Medicare beneficiaries are 65 years of age or over. There are two major components of the Medicare Program: Part A and Part B. (Compls. ¶ 6.)

Medicare Part A pays for prescription drugs only if they are administered on an inpatient basis in a hospital or similar setting. Medicare Part B is an optional program that provides coverage for some health care services not covered by Part A. 42 U.S.C. §§ 1395j through 1395w-4. (Medicare Part B is referred to as "Medicare.") (Compls. ¶¶ 7, 8.)

Medicare pays for a few categories of prescription drugs administered outside a hospital setting, including those administered by injection or infusion by physicians and their staff in the doctor's office and other outpatient settings or by other specified health care providers at other sites (collectively "physician-administered drugs"); some orally administered anti-cancer chemotherapy drugs and anti-emetics, which control the vomiting and nausea caused by such chemotherapy agents; and drugs administered through durable medical equipment such as a nebulizer (collectively "Medicare-covered"

drugs). 42 U.S.C. §§ 1395k(a), 1395x(s)(2); 42 C.F.R. § 405.517. Anti-cancer chemotherapy drugs and anti-emetics are the dominant types of physician-administered drugs covered by Medicare. (Compls. ¶ 9.)

For Medicare-covered drugs, the health care provider or pharmacist receives the lower of the charge the health care provider or pharmacist actually bills Medicare or 95 percent of the drug's average wholesale price. Medicare pays eighty percent of this amount, and the beneficiary is responsible for 20 percent as a coinsurance payment. 42 U.S.C. §§ 1395u(o), 1395*l*(a). (Compls. ¶10.)

The Medicaid Program is a program jointly funded by the federal, state and county government that is administered by the State. It pays for prescription drugs, whether administered by physicians or dispensed by pharmacies, as well as other health care services, for low-income persons. Medicaid recipients pay a copayment for covered drugs, which is a flat amount based on whether the drug is a brand or generic. (Compls. ¶11.) Soc. Serv. Law § 367-a; 18 N.Y.C.R.R. § 360-7.12. For low-income individuals eligible for both Medicare and Medicaid, Medicaid pays the person's Medicare coinsurance amount for Medicare-covered drugs. 18 N.Y.C.R.R. § 360-7.7.

Reimbursement to pharmacists for drugs dispensed under the Medicaid Program generally is limited to the lower of the "[e]stimated acquisition costs plus reasonable dispensing fees" or the "[p]roviders' usual and customary charges to the general public." 42 C.F.R. § 447.331. (Medicaid reimbursement for physician-administered drugs is handled differently, and thus not a subject of the State's lawsuit.) In New York State, Soc. Serv. Law § 367-a defines "estimated acquisition cost" as "the average wholesale price of a prescription drug...as reported by the prescription drug pricing service used by the department, less ten percent thereof..." for drugs that have no Federal Upper Limit.[2] (Compls. ¶ 12.)

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[2]A Federal Upper Limit caps the amount that a Medicaid Program can pay for some generic drugs. The "Federal Upper Limit" is defined at 42 C.F.R. § 447.332 as "150 percent of the published price for the least costly therapeutic equivalent."

EPIC is a voluntary New York State-funded and state-administered program that provides prescription drug coverage to lower income consumers who are 65 years of age or older and are not eligible for full Medicaid coverage. It covers prescription drugs dispensed by pharmacies. Individuals who choose to participate in the program must pay a copayment for each drug purchase based on the price charged for the drug. A participant's copayments for the year are subject to an upper limit based on the participant's income. (Compls. ¶ 13.)

For drugs for which no Federal Upper Limit has been established or which cannot be replaced by a generic for a particular patient, EPIC reimburses the dispensing pharmacy at the lower of 90 percent (95 percent before 2002) of average wholesale price or the pharmacy's usual and customary charge to the general public. Exec. Law § 547-j(1)(b). (Compls. ¶ 14.)

B. Defendants' Scheme

Periodically, defendants report pricing information for each of their drugs to national drug pricing services or compendia ("compendia"), including Red Book, MediSpan and First Data Bank. The compendia publish an amount for each drug which is identified as "average wholesale price." (Compls. ¶¶ 15, 16.)

Pharmacia has reported to the compendia an amount as average wholesale price for each of its drugs (which should be the price a physician or pharmacist pays a wholesaler, distributor or other middleman), although it may now report information giving it a different name. (The amount Pharmacia reports to the compendia is referred to as the "reported average wholesale price.") The compendia publish Pharmacia's reported average wholesale price essentially without modification ("published average wholesale price"). (Pharm. Compl. ¶ 15, 16.)

GSK and Aventis have reported to the compendia an amount as the wholesale acquisition cost for each of their drugs (which should be the price a wholesaler, distributor or other middleman pays the defendant). Previously, Aventis and GSK each reported amounts to the compendia using various labels, that either (1) they called "average wholesale price" or its equivalent, which the compendia

published as "average wholesale price," or (2) were another measure of cost or price that the compendia used as the basis for determining the average wholesale price that they published for these defendants' drugs. The compendia add a standard markup to the reported wholesale acquisition cost and publish that amount as the drug's "average wholesale price" (Av. & GSK Compls. ¶¶ 15-17.) (The amount Aventis or GSK report to the compendia is referred to as the "reported wholesale acquisition cost.")

Each defendant knows of and relies on the practices of the compendia of publishing the reported average wholesale price without substantial modification and of using the reported wholesale acquisition cost to determine the amount they will publish as a drug's average wholesale price. (Av. & GSK Compls. ¶ 18; Pharm. Compl. ¶ 17.) With this knowledge, defendants have reported grossly inflated average wholesale prices and wholesale acquisition costs. Defendants have provided this false information knowing that it would be used by the State to determine the reimbursements paid for drugs to providers and the copayments paid by consumers. As such, the defendants' scheme to defraud has resulted in overpayments by the State to physicians, pharmacists and other health care providers under the Medicare, Medicaid and EPIC programs and by Medicare beneficiaries and EPIC participants.

1. MEDICARE

The "average wholesale price," as published by the compendia, is virtually the only information used to determine the amount Medicare will pay a New York Medicare provider or pharmacist for a Medicare-covered drug. This has been true for over a decade, and defendants know of and rely on this practice. (Av. & GSK Compls. ¶ 20; Pharm. Compl. ¶ 18.)

Both directly and through middlemen, each defendant sells its Medicare-covered drugs to physicians, other health care providers and pharmacists. Each defendant knows the prices middlemen pay for its drugs and the amount these middlemen charge providers and pharmacists for their drugs. (Av. & GSK Compls. ¶ 21; Pharm. Compl. ¶ 20.)

The amount Pharmacia transmits to the compendia as the reported average wholesale price of each of its Medicare-covered drugs, and the amount Aventis and GSK each transmits to the compendia as the reported wholesale acquisition cost of each of its Medicare-covered drugs (which is the basis for the drug's published average wholesale price), is greatly inflated and bears no relationship either to the price middlemen pay the defendants or to the price physicians, other health care providers and pharmacists actually pay to purchase these drugs. Defendants knowingly report these false, misleading and deceptive amounts which each knows will be used to determine a false, misleading and deceptive published average wholesale price. (Av. & GSK Compls. ¶ 22; Pharm. Compl. ¶ 21.)

Physicians, other health care providers and pharmacists are routinely reimbursed by Medicare for each defendant's Medicare-covered drugs in an amount equal to 95 percent of the drug's fraudulently inflated published average wholesale price, and each defendant is aware of this fact. (Av. & GSK Compls. ¶ 23; Pharm. Compl. ¶ 22.)

The difference between the amount a physician, other health care provider or pharmacist pays for a drug and the amount Medicare (or other health care program) reimburses for that drug is profit to the provider. These profits can be enormous when the provider selects one of the defendants' drugs. In the pharmaceutical industry, this guaranteed profit is referred to as the "spread." (Av. & GSK Compls. ¶ 24; Pharm. Compl. ¶ 23.)

The complaints set forth examples of the spreads each defendant created when, in providing information to the compendia, it misrepresented and concealed the average wholesale price of its Medicare-covered drugs. These spreads were calculated based on middlemen's catalog prices, but due to price concessions each defendant makes available to physicians and other health care providers, they actually pay middlemen far less than their catalog prices for some drugs. The examples of spreads identified in the complaint are as follows:

- **Aventis**: Spreads of 44 percent for Dolasetron mesylate (Aventis' brand is Anzemet®), an anti-emetic used in conjunction with chemotherapy; and 15 percent for Docetaxel (Aventis' brand is Taxotere®), a chemotherapy agent used to treat breast cancer. In just one year, the overcharge to Medicare for Aventis' Taxotere® was $9.2 million, and the overcharge for the injectable form of Anzemet® was $20.5 million, although another company also sold this drug under the Anzemet® brand. (Av. Compl. ¶ 25.)
- **GSK**: Spreads of 72 percent for Albuterol sulfate (GSK's brand name is Ventolin®), in the form administered through a nebulizer to treat breathing difficulties caused by asthma, chronic bronchitis, emphysema, and other lung diseases; 25 percent for Granisetron HCl (SmithKline Beecham Corporation's brand name was Kytril®), an anti-emetic used to treat the nausea and vomiting caused by anticancer chemotherapy agents (in August 2000, GSK divested itself of all rights to Kytril® as a condition for the merger that created GSK); 15 percent for Vinorelbine Tartrate (GSK's brand name is Navelbine®), used to treat types of lung, breast and ovarian cancer; 11 percent for Topotecan (GSK's brand name is Hycamtin®), a chemotherapy agent used to treat ovarian cancer; and nine percent for Ondansetron HCl (GSK's brand name is Zofran®), which like Kytril® is an anti-emetic used in conjunction with anticancer chemotherapy. In just one year, the total overcharge to Medicare for GSK's Zofran®, Navelbine® and Hycamtin® and for SmithKline Beecham's Kytril® was $23.8 million. (GSK Compl. ¶ 25.)
- **Pharmacia**: Spreads of 76 percent for Doxorubicin HCl (Pharmacia's brand name is Adriamycin RDF®/PFS®), an injectable drug used to treat various cancers including breast and ovarian cancer; and 16 percent for Pharmacia's Camptosar® (Irinotecan HCl), a chemotherapy drug prescribed for colon and rectal cancer. In just one year, the overcharge to Medicare for Pharmacia's Camptosar® was $13 million. Among other Medicare-covered drugs for which Pharmacia has reported deceptive average wholesale

prices, and thereby created significant spreads, are the cancer treatments Bleomycin, Etoposide (brand name Toposar™), and Vincristine (brand name Vincasar PFS®); the anticoagulant Heparin; and the anti-fungal Amphotericin B (brand name Amphocin®). (Pharm. Compl. ¶¶ 24, 25.)

Each defendant maintains or increases the sales volume for its Medicare-covered drugs by actively marketing the spread to doctors and pharmacists. Each defendant encourages New York physicians, other New York health care providers and New York pharmacists to select its drugs by informing them of the amount of profit they can reap if they administer or dispense its drugs, a profit the defendant can guarantee the doctor or pharmacist because Medicare pays for the drugs based on the defendant's deceptive reporting of the information used to calculate average wholesale price.

Each defendant creates and markets the spread on its prescription drugs to New York doctors without the consent or knowledge of their patients and with the intent to influence the physicians' choice of drugs to administer or prescribe to their patients. (Compls. ¶ 36.)

As a consequence of defendants' deceptive reporting of false prices, Medicare beneficiaries, who are responsible for a 20 percent copayment of the amount Medicare allows for a Medicare-covered drug, often pay significantly more than 20 per cent of the uninflated price, and thus suffer significant economic injuries. (Compls. ¶ ¶33, 34.)

2. MEDICAID

As each defendant has known for years, the New York Medicaid Program reimburses pharmacist-dispensed drugs for which no Federal Upper Limit has been set exclusively on the basis of the average wholesale price reported in *First DataBank*, a compendium. Thus, by reporting to *First DataBank* false and fraudulently inflated reported average wholesale prices or inflated reported wholesale acquisition costs, which each defendant knows will be converted to published average wholesale prices, each defendant controls the reimbursement amount paid by Medicaid for these

drugs, irrespective of any change in their market prices. (Compls. ¶ 28.) By reporting false prices, each defendant causes the State to pay more for these drugs than is permitted by law. (Compls. ¶ 29.)

Each defendant fraudulently creates and markets the spread on its drugs to New York pharmacists who are Medicaid providers. Each defendant does this to induce pharmacists to recommend its drugs to Medicaid recipients and their physicians, to purchase more of its drugs, and to bill those drugs to Medicaid. Each defendant thereby offers reimbursement that it has enhanced through its fraudulent acts as the quid pro quo for recommending its drugs and, together with those providers who accept this offer, intentionally causes Medicaid to pay the falsely overstated prices. The amount of the spread on each defendant's drugs has not been disclosed to the State and to Medicaid recipients who purchase such drugs, and it has not been reflected in claims for Medicaid reimbursement. (Compls. ¶ 30.)

3. EPIC

The Department of Health sets reimbursement for drugs covered by EPIC using information from *First DataBank*. By reporting false and fraudulently inflated wholesale acquisition costs to *First DataBank*, which are the basis for its determination of published average wholesale prices, each defendant knowingly causes the EPIC Program to pay excessive amounts for covered drugs for which no Federal Upper Limit had been set. (Compls. ¶ 31.)

Each defendant manipulates and markets the spread on its EPIC-covered drugs to New York pharmacies by informing them of the increased and guaranteed profits available for dispensing its drugs. By doing this, each defendant increases or maintains its sales of these drugs. (Compls. ¶ 32, 38.)

As a consequence of defendants' reporting of inflated prices, EPIC participants, who are responsible for a copayment based on the amount the government health care program allows for the purchased drug, suffer significant economic injuries. (Compls. ¶ 34).

ARGUMENT

POINT I

THE MEDICARE ACT DOES NOT AUTHORIZE MANUFACTURERS TO REPORT FICTITIOUS AND INFLATED AVERAGE WHOLESALE PRICES.

Defendants' argument is a peculiar one that ignores all the basic tenets of statutory interpretation. First, they ignore the ordinary and natural meaning of the statutory term "average wholesale price" and instead contend that they can report an amount that has no relationship to the price health care providers pay for defendants' drugs. Second, the defendants cite nothing in the legislative history that indicates Congress intended drug manufacturers to report fictitious amounts. Third, in the absence of statutory language or supportive legislative history, defendants point to various post-enactment legislative action and inaction over a number of years to suggest Congress was aware of the full scope of defendants' inflated reporting and condoned it. Fourth, bereft of traditional statutory interpretation tools, defendants invent a policy argument that Congress intended to give the defendants unbridled discretion to report any number they wished as the basis for government reimbursement in order to subsidize health care providers. Congress never adopted such a policy.

A. Defendants' Reporting of Inflated and Fictitious Prices is Inconsistent with the Plain Meaning of "Average Wholesale Price.

Congress first adopted "average wholesale price" as the specific methodology for reimbursing Medicare-covered drugs in 1997. Previously, "average wholesale price" was the standard of reimbursement pursuant to a regulation promulgated by the Heath Care Financing Administration ("HCFA"), now known as the Centers for Medicare and Medicaid Services ("CMS"). Congress established the following standard:

> (o) ***Reimbursement*** for drugs and biologicals.
>
> (1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part [42 U.S.C. §§ 1395j et seq.]and the drug or biological is not paid on a cost or prospective

> payment as otherwise provided in this part [42 U.S.C. §§ 1395j et seq.], ***the amount payable for the drug or biological is equal to 95 percent of the average wholesale price***.

42 U.S.C. § 1395u(o) (Emphasis supplied). When interpreting a statute, the court looks "first and foremost to its text." *United States v. Pedro Alvarez-Sanchez*, 511 U.S. 350, 356 (1994); *Riley v. County of Broome*, 95 N.Y.2d 455 (2000).

Because section 1395u(o) creates a mandatory standard for reimbursement, that standard must have an ascertainable and definite meaning. Congress, however, did not define the phrase "average wholesale price" or otherwise indicate that it was intended to be a term of art.[3] Consequently, the phrase "average wholesale price" must be construed "in accordance with its ordinary or natural meaning." *U.S. v. Pedro Alvarez-Sanchez*, 511 U.S. at 357 (quoting *FDIC v. Meyer*, 510 U.S. 471, 476 (1994)); *see also Castro v. United Container Machinery Group, Inc.*, 96 N.Y.2d 398 (2001) ("words in a statute are to be given their plain meaning without resort to forced or unnatural interpretations.").

In determining the ordinary meaning of statutory language, courts routinely rely on dictionaries. *See e.g., United States v. Pedro Alvarez-Sanchez*, 511 U.S. at 357-58 (*American Heritage Dictionary*). The dictionary definition of the adjective "average" means being about midway between extremes: not out of the ordinary. . ." *Webster's Third New International Dictionary, Unabridged*, 150 (1981). The adjective "wholesale" is defined as "of or relating to or engaged in the sale of goods or commodities in quantity for resale." *Id.* at 2611. Finally, the noun "price" is defined as "the amount of money given or set as the amount to be given as consideration for the sale of a specified thing." *Id.* at 1798. In combination, the ordinary or natural meaning of the words "average wholesale price" reflects the ordinary or approximate midway point of the amount of money paid for the sale of a particular good or commodity that will be resold.

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[3]The use of the abbreviation "AWP" or the capitalized version of "Average Wholesale Price" degrades and distorts the language Congress used. The State, therefore, abjures their use.

According to defendants, by failing to define the phrase "average wholesale price," Congress intended to adopt a meaning that would allow manufacturers to report any amount they wished, including fictitious and inflated amounts that do not reflect contract prices, discounts, rebates, credits or other price concessions that reduce health care providers' actual costs. No reasonable interpretation of the statute could envision the ordinary or natural meaning of the phrase "average wholesale price" to reflect the amount of money paid for a commodity at an upper extremity or not actually paid by any purchaser. Yet this is precisely what defendants say Congress intended when it used the words "average wholesale price" in the statutory standard for Medicare drug reimbursement.

"Reimbursement" means "to make restoration or payment of an equivalent to." *Id.* at 1914. Payment to a provider of an equivalent of the price of purchasing a drug does not include a profit to the provider. *See Lupron* MDL., *5 n. 15. ("I do not understand why a doctor, who is being paid to administer a drug to a patient, is entitled to earn a profit on the drug he injects."). Defendants' argument invites this court to deviate from the ordinary meaning of the statutory language. The court should decline to do so.

B. The Legislative History of "Average Wholesale Price" Does Not Support an Interpretation Other than its Ordinary Meaning.

In interpreting a statute, "resort to extrinsic matter is inappropriate when the statutory language is unambiguous and the meaning unequivocal. While legislative intent is the great and controlling principle, it should not be confused with legislative history, as the two are not coextensive." *Barrett v. State of New York*, 161 N.Y.2d 61, 67 (1990) (internal citations omitted); *Sega v. State of New York*, 60 N.Y.2d 183 190-191 (1983) (same). Because the plain meaning of Congress' phrase "average wholesale price" is not ambiguous, there is no reason to go beyond the text to interpret the statute.

If the court elects to examine the legislative history, it will find that, at most, defendants' 25-page recitation of the "history" of Congress' adoption of the reimbursement standard chronicles what

Congress ***might*** have known and what ***might*** have influenced Congress if it had known of the various materials on which defendants rely to show Congress' intent. (These materials consist primarily of executive branch reports, magazine articles, and a footnote in a decade-old brief.) From nothing more than the possibility that Congress was generally aware that the published average wholesale price for some drugs was inflated, defendants conclude that Congress condoned and acquiesced to the practice of inflating reported prices. Such a leap in logic contravenes basic principles of statutory construction and has been rejected by two federal courts in average wholesale price litigation. *Lupron* MDL, 2003 WL 22839966 at *5 (rejecting the argument that Congress would condone the practice of inflating wholesale drug prices). *Cf. Pharm. Indus.* MDL, 263 F. Supp. 2d at 187 ("rejecting significance of Congress' failure to disturb widespread practice of inflating wholesale drug prices).

Defendants would have the Court believe that the fact that Congress set reimbursement at 95 percent of average wholesale price meant that Congress was acquiescing to defendants' reporting of fictitious prices. Defendants are wrong. To determine what Congress intended in 1997 when it adopted 95 percent of average wholesale price as the reimbursement standard, it cannot venture beyond the statutory language. Its inquiry must focus on Congress' contemporary actions. *See Pension Benefit Guaranty Corp. v. LTV Corp.* 496 U.S. 633, 650 (1990) (quoting *United States v. Price*, 361 U.S. 304, 313 (1960) ("subsequent legislative history is a 'hazardous basis for inferring the intent of an earlier' Congress"); *see Majewski v. Broadalbin-Perth Cent. Schl. Dist.*, 91 N.Y.2d 577, 587 text and n. 2 (1998).

Before Congress adopted the average wholesale price statutory reimbursement standard in 1997, HCFA's regulatory standard applied: the lower of the average wholesale price or the estimated acquisition cost. Because of the administrative burdens created by the process of estimating acquisition cost, HCFA never implemented the estimated acquistion cost portion of the standard.

That year, Congress also rejected an entirely different approach to determining reimbursement amounts which the Administration had proposed. This proposal was even more complicated than the

existing and never-implemented regulatory standard. Early in 1997, the Clinton Administration proposed changing Medicare drug reimbursement from the simple average wholesale price-based model in operation to a complex system that would reimburse based on the lowest of actual acquisition cost to the provider, average wholesale price, median national acquisition cost, or an otherwise determined amount. OIG "Excessive Medicare Payments for Prescription Drugs," OEI-03-97-00290 (1997) at 2. (Fire. Aff. Ex. 14.) Congress rejected this approach.

Without citing any factual or legal basis, defendants suggest that Congress rejected the Administration's proposal because Congress intended to allow the manufacturers to manipulate the reimbursement system by reporting average wholesale price information that did not reflect health care providers' actual costs. Without a concrete basis for such a hypothesis, the Court must reject it. *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. at 650 (relying on failed legislative proposals treads on "dangerous ground"); see also *Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers*, 531 U.S. 159, 170 (2001) ("[a] bill can be proposed for any number of reasons, and it can be rejected for just as many others.").

A far more rational explanation for the Clinton proposal's defeat is that, following HCFA's inability to implement a significantly less complicated approach to reimbursement, Congress rejected complexity in favor of simplicity: enacting the "average wholesale price" standard which had been in practice.

Defendants suggest that in 1997 Congress was well aware that drug manufacturers were reporting fictitious prices. However, the information before Congress when it adopted the statutory reimbursement standard was extremely limited as to the number of drugs actually affected by the manufacturers' price-reporting manipulation and showed enormous variation in the amount by which the published average wholesale prices exceeded health care providers' actual acquisition costs. This legislative history does not support a finding that Congress intended to do anything other than adopt a

standard that has the plain meaning conveyed by the phrase "average wholesale price," i.e., the price health care providers commonly pay for the drugs they administer or dispense.

The only information about the manipulation of average wholesale price that was definitely before Congress when it enacted the statutory standard was reflected in the House Committee Report concerning the Balanced Budget Act, a more than thousand-page document only one paragraph of which pertained to the Medicare drug reimbursement standard. In this paragraph, the House noted that in a recent, unidentified report issued by the HHS Inspector General ("OIG"), the ten top oncology drugs were reimbursed at 20 to 1000 percent above their acquisition costs. Balanced Budget Act of 1997, Report of Comm. on the Budget to accomp. HR2015, Rpt. 105-149 (1997) at 1354. (Def. Ex. S.) ("House Report").

This statement reflected no information on the other 400-plus drugs covered by Medicare. The only inference that can be supported by Congress' recitation of this limited information is that Congress had some notion that there was a problem with the amount paid for a small number of drugs. Moreover, consistent with the record before Congress, the cited overpayments could have been the result of deceptive conduct by a handful of manufacturers or an industry-wide deceptive practice. Judge Stearns noted in the *Lupron* MDL, "the recognition on the part of government regulators [including Congress] of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct." 2003 WL 22839966 at *9 n.19.

Again, an alternative explanation is significantly more likely: Congress knew a problem existed with the amounts paid for some Medicare-covered drugs, but did not have sufficient information about its scope to devise a solution that ended the overpayments with precision..[4] Once

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[4]Some contended that some drug prices were not inflated. In 1991, oncologists informed HCFA that some drugs were not inflated and that small practices did not receive the discounts available to groups and large practices. Medicare Program; Fee Schedule for Physicians' Services, 56 Fed. Reg. 59502-01, printed pages 58-59 (1991) (Fire. Aff. Ex 5.) Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, Subcomm. on Health and

again, Congress opted for simplicity by discounting all drug reimbursements by five percent of average wholesale price. It also required HCFA to study the effect of the five-percent discount on reimbursement amounts in the future.[5] This was a tentative first step toward protecting Medicare and beneficiaries from the manipulation that caused them to pay unnecessarily large amounts for essential drugs. It does not indicate Congress chose to "deliberately invite[] the very fraud of which defendants are accused." *Lupron MDL*, 2003 WL 22839966 at *5.

There is no other Congressional history for the 1997 Act. There is no evidence in the 1997 legislative record that shows whether Congress was even aware of the executive branch reports and other general information defendants cite. Additionally, even if Congress had been aware of these materials, they would not have supported defendants' strained interpretation of the statute. For example, defendants cite testimony of the Secretary of the Department of Health and Human Services referring to average wholesale price as a "sticker" price. This proves nothing. As Judge Stearns noted, "there is a difference between a sticker price and a sucker price." *Lupron MDL* at *9 n. 19. The Secretary's cryptic message did not inform Congress of the nature or the size of the price concessions available to physicians or whether they were available to all physicians. Similarly, defendants refer to one of the few pre-1997 studies that addressed Medicare-covered drugs, as

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Subcomm. on Oversight and Investigations of House Comm. on Energy and Comm., Serial No. 107-65 (2001), at 88 (testimony of Thomas A. Scully, CMS Admin., describing oncologists' 1991 representation to HCFA); at 89 (statement of Rep. Greenwood rejecting an across-the-board 15 percent discount because some average wholesale prices were "straight."). (Def. Ex. N.)

[5]The House Report referred to the price compendia, but this has no bearing on the interpretation of the phrase "average wholesale price." The Report stated, "The Committee intends that the Secretary, in determining the average wholesale price, ***should take into consideration*** commercially available information ***including*** such information as may be published or reported in various commercial reporting services." House Report at 1354) (Def. Ex. S.) (Emphasis supplied.) The Committee clearly did not intend the Secretary simply to lift a number out of a compendium. Otherwise, the words "taking into consideration" and "including" have no meaning.

opposed to those dispensed by a pharmacist and covered by Medicaid. This report conveyed almost no information because it was based on the drug-purchasing experience of only five practices and a "limited" survey. OIG, "Physicians' Costs for Chemotherapy Drugs," A-02-91-01049 (1992) at 4 and Appendix I. (Def. Ex. G.) Finally, even if Congress had been aware of the pre-1997 Medicaid studies defendants cite, there is no basis in the legislative record to suggest that Congress knew, or even assumed, that physicians had access to the same discounts available to pharmacists. (See n.4 *supra.*)

In short, the legislative history is entirely devoid of any support for deviating from the ordinary and natural meaning of "average wholesale price" and "reimbursement."

C. Post-Enactment History Is Irrelevant and Does Not Support Defendants' Position.

Defendants' reliance on post-1997 legislative and administrative developments to support their argument that Congress intended manufacturers to report inflated average wholesale price is misplaced. It is a well established rule of statutory construction that "the interpretation given by one Congress (or a committee or Member thereof) to an earlier statute is of little assistance in discerning the meaning of that statute." *Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 185 (1994) (quoting *Public Employees Retirement System of Ohio v. Betts*, 492 U.S. 158, 168 (1989). Indeed "subsequent legislative history is a 'hazardous basis for inferring the intent of an earlier' Congress." *Pension Benefit Guaranty Corp. v. LTV Corp.* 496 U.S. 633, 650 (1990) (quoting *United States v. Price*, 361 U.S. 304, 313 (1960). *See Majewski v. Broadalbin-Perth Cent. Schl. Dist.*, 91 N.Y.2d 577, 587 and n. 2 (1998).

Moreover, Congressional post-enactment action and inaction do not demonstrate that it acquiesced in the manufacturers' reporting of information to the compendia that resulted in published average wholesale prices, and consequently reimbursement amounts, that did not reflect health care providers' real costs. Defendants assert that, between 1997 and 2003, when average wholesale price

was eliminated as the basis for drug reimbursement, Congress failed to take any action to stop manufacturers from reporting inflated average wholesale price information and that this silence must be taken as condonation of the manufacturers' deceptive conduct.

Congress, however, was hardly dormant on Medicare drug reimbursement issues between 1997 and 2003. During this period, Congress held hearings and ordered studies of the reimbursement process. These actions do not indicate Congress' approval, but rather its dissatisfaction with the outcomes caused by the statute's operation, specifically the excessive drug reimbursement payments imposed on the Medicare Program and beneficiaries. Yet, according to defendants' argument, the statute was operating precisely as Congress had intended in 1997.

With all the legislative consideration of the issue between 1997 and 2003, the one notion absent from any statement, study, hearing or other expression is that Congress meant the manufacturers to have unfettered discretion to inflate average wholesale prices and, consequently, drug reimbursement. This "contradicts what [Congress] did in the Medicare program, which was literally to provide a co-payment requirement on the patient that was supposed to be one-fifth of the actual cost . . ." A Broken System for Patients and Taxpayers, Subcomm. on Health and Subcomm. on Oversight and Investigations of House Comm. on Energy and Comm., Serial No. 107-65 (2001) at 8 (statement of Rep. Tauzin, Chair. at 96). ("2001 Hearing".)

Defendants point to specific congressional actions after 1997 that they suggest support their view that reporting inflated average wholesale price information was permitted by the 1997 Act.[6]

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[6]Senator Ashcroft's 2000 bill, on which defendants rely, (Def. Mem. at 26) was never reported out of committee. The letter of the 89 Members of Congress (Def. Ex. V) expressed concern over the effect of using uninflated average wholesale prices on patients' access to services, recommending that CMS delay implementation of its plans because some type of regulatory process would be appropriate first. These members never suggested that the Secretary was not empowered to take the proposed action without a study and comment period, only that they thought it was ill-advised.

Defendants argue that enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Public Law 106-554, indicates Congress approved of defendants' price reporting practices. This Act mandated that the General Accounting Office ("GAO") study Medicare drug reimbursement; imposed a moratorium on decreases in the Medicare drug payment rates until the Secretary reviewed the GAO study;[7] and authorized CMS to modify the reimbursement system. *See* BIPA Sections 429 (a)-(c). These actions demonstrate that Congress recognized that the system was not working correctly and that it had insufficient information to design a remedy. Congress' actions hardly constitute approval of the manufacturers' deceptive conduct. If Congress intended drugs to be reimbursed on an inflated average wholesale price, there would have been no reason for further study and a directive to modify the reimbursement system.

At a September 21, 2001 congressional hearing, which significantly was entitled "A Broken System for Patients and Taxpayers," Thomas Scully, CMS Administrator, testified that studies showed that drug reimbursement was "vastly higher" than providers' acquisition costs. "That means Medicare beneficiaries, through their premiums and cost sharing, and the U.S. taxpayers are spending far more than the ***'average' price that we believe the law intended them to pay.***" 2001 Hearing at 87. (Emphasis added.) Administrator Scully went on to note that:

> [t]he AWP is ***intended*** to represent the average price at which wholesalers sell drugs to their customers, which includes physicians and pharmacies. Traditionally, AWP has been based on prices reported by drug manufacturers and published in compendia such as the *Red Book*, ... However, manufacturers and wholesalers ***increasingly*** give physicians and providers discounts that reduce the actual amount that the physician or provider actually pays for the drugs. These discounts are ***not*** reflected in the published price and reduce the amount providers actually pay to levels far below those prices published in the *Red Book*. Furthermore, use of the AWP, as reported by manufacturers to companies which compile such prices creates a situation where a manufacturer can, for certain drugs, increase the reported AWP and, in turn, offer physicians a deeper discount.

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[7]Contrary to defendants' assertion, Congress did not impose a moratorium on decreases in drug reimbursement amounts, but on reimbursement rates, *i.e.*, on the reimbursement ***rate*** of 95 percent. (Def. Mem. at 26-27.)

Id. at 88. (Emphasis supplied). This describes an evolving and significant landscape that did not exist in 1997.

In November 2003, Congress enacted legislation terminating use of average wholesale price as the standard for Medicare drug reimbursement. In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress overhauled Medicare's prescription drug provisions and, starting in 2005, will abandon use of the average wholesale price reimbursement methodology for covered drugs under Medicare. The Conference Report provides a detailed summary of the existing law and conclusively refutes defendants' suggestion that Congress, in any way, had intended to condone or acquiesce in defendants' practice of reporting inflated average wholesale prices. The Conference Report notes that "[t]he AWP is intended to represent the average price used by wholesalers to sell drugs to their customers." Medicare Prescription Drug, Improvement and Modernization Act of 2003, Comm. of Conference, 108 H. Rpt. 381 (2003) at 582. (Fire. Aff. Ex. 18.)

Congress' decision to scrap average wholesale price as the reimbursement standard demonstrates that Congress did not previously intend to endorse defendants' practice of reporting inflated average wholesale prices. To the contrary, the recently enacted Medicare legislation represents the culmination of Congress' and the federal government's recognition that the average wholesale price payment system had been manipulated. This cannot be reconciled with an intent that manufacturers were free to inflate their published average wholesale prices while discounting providers' prices in order to sell more products.

It is impossible to discern any congressional intent to support the federal government paying exorbitantly inflated reimbursement for prescription drugs. To accept defendants' government knowledge argument and their version of the so-called public record surrounding the use of average wholesale prices, this Court would necessarily have to embrace the remarkable notion that Congress

acquiesced in the pharmaceutical companies having unfettered discretion to set the federal government's reimbursement rate. Such a conclusion is unwarranted.

D. Defendants' Policy Argument -- That Congress Intended to Have Drug Reimbursement Payments Subsidize Oncologists' Professional Fees -- Contravenes the History of the Average Wholesale Price Standard.

Traditional rules of statutory construction do not support defendants' argument that in 1997 Congress intended manufacturers to report any number they wished as the average wholesale price of their drugs and, thereby, cause the amount Medicare and the beneficiaries pay as reimbursement for the drugs to be substantially greater than the health care providers' cost in purchasing the drugs. Defendants, therefore, resort to a policy argument to suggest that Congress wanted to subsidize the professional fees Medicare and the beneficiaries pay physicians and their staff to administer the covered drugs, which defendants argue are inadequate. (Def. Mem. at, e.g., 19, 21.)[8]

Defendants' reasoning fails. First, policy arguments cannot overturn an interpretation reached through straightforward statutory construction, except where statutory construction would produce a bizarre result. *Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 188 (1994). Such is not the case here. Second, if the court considers defendants' policy argument, it will find that the history of the average wholesale price standard does not support it. When HCFA initially adopted average wholesale price as the reimbursement standard, which preceded Congress' enactment of this standard, it was precluded by federal law from subsidizing the doctors' professional fees through drug reimbursement overpayments. HCFA rejected the express suggestion by oncologists to build a subsidy for their fees into the drug reimbursement standard. Finally, Congress never demonstrated any intention to disturb HCFA's judgment.

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[8]Defendants argue that there is a "long-standing linkage between Medicare reimbursement for physician-administered drugs and reimbursement for the professional services of oncologists" and that the federal government has made a "deliberate policy choice" to use drug reimbursement payments to cover otherwise unreimbursed costs, including allegedly inadequately compensated professional fees.

The Supreme Court has held that "policy considerations cannot override our interpretation of the text and structure of the Act, except to the extent that they may help to show that adherence to the text and structure would lead to a result 'so bizarre' that Congress could not have intended it." *Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. at 188. Here, the policy considerations are irrelevant because no bizarre result would flow from adherence to the statute's text and structure. In fact, adherence to the Act's text and structure results in the fiscally sound outcome that government and private individuals do not overpay for Medicare-covered prescription medication.

If the Court nevertheless entertains defendants' policy arguments, it will find them without support. Prior to 1991 when HCFA's drug reimbursement standard was promulgated,[9] Medicare reimbursed for physician-administered drugs and paid a fee for the physician's office visit at a "reasonable charge," which HCFA interpreted as the customary and prevailing rate. In 1989, Congress amended the Medicare Act to require HCFA to develop a physician's fee schedule to cover all aspects of the professional services rendered to Medicare beneficiaries by physicians and their staff, replacing the reasonable charge payment system. Congress further mandated that the new schedule be budget neutral (within $20 million per year).[10] It was silent as to the reimbursement for physician-administered drugs. Omnibus Budget Reconciliation Act of 1989, 101 P.L. 239, §§6101, *et seq.*, 103 Stat. 2106 (1989) (amended, 101 P.L. 508, 104 Stat. 1388 (1990).

In 1991, HCFA proposed regulations for a physicians' fee schedule. While Congress required professional services and various practice expenses, including supplies, to be included in the fee schedule, HCFA determined that drug reimbursement costs would be paid separately. Medicare

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[9]Defendants erroneously state that drugs were first covered under Medicare Part B in 1989 (Def Mem. at 34). In fact they have been part of the program since 1965. 89 P.L. 9733 §§ 1832(a), 1833, 1842(b), 1861(s) (1965).

[10]Congress required budget neutrality in the first year of the fee schedule's operation, but it would serve "as the basis for all future updates in payment." Medicare Program, Fee Schedule for Physicians' Services, 56 Fed. Reg. 25792, (1991), printed pages 8-9, 51.

Program; Fee Schedule for Physicians' Services, 56 Fed. Reg. 25792 (1991), printed pages 8-9, 16, 18-19, 51. ("1991 Proposed Regs."). (Fire. Aff. Ex. 4.) HCFA covered drugs under a separate reimbursement system to avoid having to squeeze this cost into the fee schedule, which some physicians asserted was already inadequately funded. *Id.* at printed page 93.

Once HCFA separated drug reimbursement from the types of expenses that had to be budget neutral, including professional fees, it was effectively foreclosed from hiding a portion of the physician's fee in the drug reimbursement payment. Otherwise, those aspects of professional fees subsidized by drug reimbursement overpayments would have evaded Congress' budget neutrality requirement applied to all payments for professional services connected to the administration of the covered drugs. Whether the fees were sufficient to compensate physicians for their services, Congress had the authority to determine the total amount Medicare and the beneficiaries would pay for these professional services, and the drug manufacturers did not have the authority to supplant Congress' judgment on this matter.

The history of HCFA's promulgation of the 1991 drug reimbursement standard futher demonstrates that the agency refused to incorporate any aspect of payment for professional fees into drug reimbursement, although it was importuned to do so. In its proposed regulations, HCFA did not intend to pay any physicians, including oncologists, separately for the administration of any covered drug during an office visit, and to reimburse covered drugs at 85 percent of average wholesale price. In comments on the proposed regulations, oncologists objected strongly to the "double hit" of a 15 percent discount on average wholesale price and the absence of a special fee for the administration of chemotherapy drugs in addition to the office visit fee. The oncologists argued that while some drugs could be obtained at less than the proposed 15 percent discount, others were not discounted at all; significant discounts were not available to individual practitioners, as opposed to groups or large practices; reimbursement should specifically cover the cost of breakage, waste, shelf-life limitations and inventory costs; and without an add-on to cover shortfalls in service fees (the proposed rule had

not provided an extra payment for administering the drug), some physicians would only provide treatment in hospital settings or require the patient to purchase the drugs and take them to the `treatment. Medicare Program; Fee Schedule for Physicians' Services, 56 Fed. Reg. 59502-01 (1991), printed pages 58-59 ("1991 Final Reg."). (Fire. Aff. Ex 5.)

In the final rule, HCFA addressed the oncologists' concern about shortfalls in professional fees not by adopting their suggestion of a subsidy built into the drug reimbursement payment but instead by providing a separate fee for the administration of chemotherapy treatments in addition to an office visit fee. It also provided that covered drugs would be reimbursed at the lower of estimated acquisition cost and 100 percent of average wholesale price. HCFA explicitly allowed the calculation of estimated acquisition cost to take into account "indirect costs such as inventory costs, waste, and spillage," but not an add-on to supplement the professional fees. 1991 Final Reg at printed page 59. [11]

Neither Congress nor HCFA altered HCFA's 1991 decision to separate professional fees from drug reimbursement. Each payment system remained self-contained. Defendants' policy justification for their deceptive conduct fails in light of this history.

POINT II

THE NEW YORK LEGISLATURE DID NOT INTEND MEDICAID AND EPIC DRUG REIMBURSEMENT TO BE BASED ON FICTITIOUS AND INFLATED AVERAGE WHOLESALE PRICES.

Just as Congress did not acquiesce in defendants' scheme, there is nothing in the language or history of Soc. Serv. Law § 367-a (Medicaid) or Exec. Law § 547-j (EPIC) that remotely supports defendants' argument that the New York State Legislature acquiesced in defendants' deception and intended to pay inflated prices for pharmacist-dispensed drugs under Medicaid or EPIC based on inflated published average wholesale prices. To reach defendants' conclusion, the Court would have

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[11]The logical extension of defendants' argument is that pharmacists' dispensing fees would be subsidized at the same rate as physicians' professional fees. However, there is no support in the statutory or regulatory text or history to support subsidizing pharmacists' fees.

to determine that when the New York State Legislature instructed the New York State Department of Health to use a compendium's published average wholesale price, it intended the State to contract and pay a commercial enterprise for entirely fictitious pricing information to use as the Medicaid and EPIC payment standards. This is hardly credible.

Defendants offer a potpourri of arguments that the New York State Legislature condoned the defendants' reporting of inflated average wholesale prices. None are persuasive. Defendants' assertion that the New York State Department of Social Services ("Department") could have gotten additional information about real world acquisition costs (Def. Mem. at 28-29) is irrelevant to the question of whether the New York State Legislature acquiesced in defendants' scheme. Defendants do not show that (1) the Department ever obtained these data; (2) if the Department did obtain the data, it ever provided them to the Legislature; or, (3) the Legislature's decision-making was affected by it. Without such a showing, the Department's right to obtain additional information does not enter into the analysis of the Legislature's intent.

Moreover, that the Department did not pursue information about health care providers' acquisition cost can be explained given that Medicaid is a joint federal-state program and Congress had retained average wholesale price as the basis for drug reimbursement under the all-federal Medicare program. The Department could reasonably conclude that Congress had adopted the average wholesale price standard expecting manufacturers to submit accurate information as the basis of government drug reimbursements. While CMS may have suggested to state agencies that administer the Medicaid program in their states that some average wholesale prices were inflated, it did not foreclose the use of this standard. Indeed, many states use average wholesale price as their Medicaid standard.

In a similar vein, defendants argue that the Legislature acquiesced in the inflation of the published average wholesale price because it established actual acquisition cost as the standard for physician-administered drugs, and used average wholesale price reimbursement only for pharmacist-